DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 14, 2014

REMOTE DIAGNOSTIC TECHNOLOGIES LTD
Leigh Cornock
Director of System Engineering and Tests
The Old Coach House, The Avenue, Farleigh Wallop
Basingstoke, RG252HT GB

Re: K133973
Trade/Device Name: TEMPUS PRO WITH ENHANCED FEATURES
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including St-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: December 23, 2013
Received: July 14, 2014

Dear Leigh Cornock,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

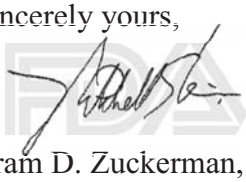
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133973

Device Name: Tempus Pro

Indications for Use:

The Tempus Pro is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for: 3 & 5 Lead ECG monitoring; 12 Lead ECG recording; real-time arrhythmia detection / alarming; QT measurement / alarming and ST measurements / alarming; impedance pneumography; non-invasive blood pressure (NIBP); end-tidal CO2 (ETCO2) and respiration rate; pulse oximetry (SpO2); contact temperature; and invasive pressure.

The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).

The device is indicated for adults, paediatrics and neonates.

Prescription Use _√_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness

5.1 Submitter's Information

The submitter of this abbreviated pre-market notification is:

Name:	Remote Diagnostic Technologies Limited
Address:	The Old Coach House, Farleigh Wallop, Basingstoke, RG25 2HT, United Kingdom
Company Phone No:	+44 (0) 1256 362 400
Company Fax No:	+44 (0) 1256 362 415
Contact Person:	Dr Leigh Cornock (Director of Systems Eng. & Test)
Date summary prepared:	9th July, 2014

5.2 Device Identification

Device Trade Name:	Tempus Pro
Common Name:	Patient Monitor (with arrhythmia detection or alarms)
Class:	II
Classification Panel:	74
Product Code:	MHX
Regulation Number:	870.1025

5.3 Device Description

The Tempus Pro is a multi-parameter vital signs monitor designed for use in pre-hospital care and remote clinical locations by trained healthcare professionals. It provides 3&5 lead ECG monitoring, 12 lead ECG recording, real-time arrhythmia detection / alarming, QT measurement / alarming and ST measurements / alarming pulse oximetry, non-invasive blood pressure, sidestream capnometry, 2 channels of contact temperature, impedance respiration, up to 4 channels of invasive pressure and user configurable alarms.

In addition, it provides the ability to transmit all vital signs data via wired or wireless connections to a software system (called i2i) expected to be based in a facility far from the user e.g. a response centre facility. In addition to sending all vital signs, the system can also send pictures or video via an integrated camera, geographic position by an integrated GPS receiver and voice via a wired or wireless headset.

5.4 Indications for Use

The following indications for use for the Tempus Pro remain unchanged from the previously cleared Tempus Pro apart from the addition of the arrhythmia detection, ST and QT measurement / alarming features,

> "The Tempus Pro is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for: 3 & 5 Lead ECG monitoring; 12 Lead ECG recording; real-time arrhythmia detection / alarming; QT measurement / alarming and ST measurements / alarming; impedance pneumography; non-invasive blood pressure (NIBP); end-tidal CO2 (ETCO2) and respiration rate; pulse oximetry (SpO2); contact temperature; and invasive pressure.
>
> The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).
>
> The device is indicated for adults, paediatrics and neonates."

5.5 Comparison with Cleared Device

The intended use and indications for use, plus the fundamental technology used in the Tempus Pro device, remain essentially unchanged by the addition of optional enhanced software feature to the ECG monitoring capability, which is specifically:

- Arrhythmia detection and alarms
- ST Elevation and depression measurement and alarms
- QT Interval measurement and alarm

5.6 Substantial Equivalence

In adding these optional features, substantial equivalence to the previously cleared Tempus Pro (K130773) has been claimed as well as substantial equivalence to the following predicate devices:

- Arrhythmia detection - Mindray iPM Patient Monitor (K123074)
  - Schiller Welch Allyn 1500 Patient Monitor (K101619)
  - Mortara surveyor central system (K131929)
- QT and ST measurement - Philips Medical IntelliVue Patient Monitor MP2 (K120366)

With respect to arrhythmia analysis and alarms, ST elevation and QT interval measurements, the implementation of algorithms utilized in previously 510(k) cleared devices, plus the additional alarm feature, were evaluated in accordance with FDA guidance on arrhythmia detection and alarm.

This guidance calls for use of the FDA recognized consensus standard EC57 (FDA Rec No: 3-118), which defines methods of presenting results when testing against specified ECG databases. A summary report demonstrating compliance with the guidance and associated standard is presented as part of this 510(k) submission.

5.7 Summary of Non-Clinical Testing

The above modifications are software only and have been made under well-established design control procedures, which ensure that appropriate risk management processes have been carried out to determine their impact and ensure that appropriate verification/ validation testing is performed.

The non-clinical testing carried out in relation to addition of the enhanced features described above is summarized in the following table:

Area	Testing Performed
Safety	This is a minor software only change so no impact on the safety of the device. The device has previously been tested to IEC 60601-1.
Defibrillation and electrosurgical protection	This is a minor software only change so no impact on the performance of the device. The device has previously been tested for operation with a defibrillator and operation with an electro-surgical unit according to IEC 60601-1 (and relevant particular standards).
Environmental	This is a minor software only change so no impact on the performance of the device. The device has previously been tested to a range of environmental (temperature, altitude, humidity, vibration, shock) tests according to RTCA DO-160, MIL810, EN 1789, EN 13718-1, EN 60068.

Area	Testing Performed
Ingress Protection	This is a minor software only change so no impact on the performance of the device. The device has previously been tested to IEC 60529 for solid and water ingress.
ECG monitoring	This is a minor software only change so no impact on the performance of the device. No change is made to the ECG board, applied parts, or software relating to communication with the ECG board Testing to AAMI EC11 & EC13 and IEC 60601-2-25 & IEC 60601-1-27 has previously been performed.
EMC	This is a minor software only change so no impact on the performance of the device. The device has previously been tested to IEC 60601-1-2 for emissions and immunity including 20 V/m radiated immunity.
Alarms	This is a minor software only change so no impact on the performance of the device. The alarm physical functions of the product have previously been tested to IEC 60601-1-8.
Comparative testing to predicates	Comparative testing has been performed to demonstrate that the performance of the device is equivalent to the predicates.
Software	The requirements of the FDA document *Guidance for the Content of Premarket Submissions for Software in Pre-Market Submissions* has been applied. In addition, the requirements of IEC 62304 have been addressed.
Bench testing	All parameters of the device have been tested to confirm they operate to specification across their stated performance range and across their stated temperature range.
Bench testing	The product has been bench tested to confirm that all data is transmitted reliably and accurately.

In each case the results of this testing confirmed that acceptance criteria defined by the relevant standard, or other appropriate reference document had been met.

With respect to usability, no additional user validation was considered necessary, as the Tempus Pro is almost identical to the predicate Tempus Pro in terms of physical and interface features, including size and weight, user interface data layouts, button styles, menus, and layout of connectors, resulting the physical interaction with the device being unchanged.

5.8 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket Notification, Remote Diagnostic Technologies Limited conclude that the Tempus Pro Patient Monitor with the enhancement of arrhythmia detection and alarms is safe and effective, and substantially equivalent to the previously cleared version of this device and other cleared devices used as predicates.